UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
McALLEN DIVISION

UNITED STATES OF AMERICA	§	
	§	
v.	§	**Criminal No. M-14-1612-S1**
	§	
MARIBEL QUINTERO	§	

SUPERSEDING INDICTMENT

THE GRAND JURY CHARGES:

Introduction

At all times relevant to this Indictment:

1. The United States Food and Drug Administration regulated, among other things, the manufacture and distribution of devices in the United States according to the provisions of the Food Drug and Cosmetic Act, Title 21 United States Code, Section 301, et seq. (the "FDCA").

2. Title 21, United States Code, Section 321(h)(3) defines "device" as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or similar or related article, including any component, part, or accessory, which is intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent on being metabolized for achievement of its primary purposes.

3. Devices were classified into one of three categories, Class I (lowest risk), II, or III (highest risk). 21 U.S.C. § 360c. A device's class determines the type of regulatory controls to which it was subject and any process it had to go through prior to marketing. With the exception of certain devices that are exempt from premarket review, devices that came on the market after May 28, 1976 are automatically classified into Class III as a matter of law, and require full premarket approval. 21 U.S.C. §§ 360c(f)(1) and 360e(a). Furthermore, the transitional provisions of the

FDCA classified injectable silicone as a Class III device that requires full premarket approval. 21 U.S.C. § 360j(l)(3)(D)(i); 42 Fed. Reg. 63472 (Dec. 16, 1977).

4. A device was adulterated if it was a Class III device and it had not received FDA approval, and was not exempt from the requirement of FDA approval. 21 U.S.C. § 351(f)(1).

5. A device was misbranded if, among other things, it failed to bear adequate directions for use. 21 U.S.C. § 352(f)(1). "Adequate directions for use" means directions under which a layman can use a device safely and for the purposes for which it was intended. 21 C.F.R. § 801.5.

6. A device was also deemed to be misbranded if all words, statements, or other information required by or under authority of the FDCA to appear on the label or labeling did not appear in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. 21 U.S.C. § 352(c). Regulations promulgated pursuant to the FDCA state that "[a]ll words, statements, and other information required by or under authority of [the FDCA] to appear on the label or labeling shall appear thereon in the English language." 21 C.F.R. § 801.15(c)

7. Title 21, United States Code, Section 331(c) prohibits the receipt in interstate commerce any food drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

8. Defendant Maribel Quintero is not a licensed medical practitioner.

9. Defendant Maribel Quintero would administer injections of liquid silicone into humans to affect the structure of the buttocks.

10. The liquid silicone used by defendant Maribel Quintero is a "device" subject to the regulation of the Food and Drug Administration.

11. The liquid silicone received by defendant Maribel Quintero was a Class III device that

required an FDA-approved application and lacked such approved application.

12. The liquid silicone received by defendant Maribel Quintero was misbranded in that: (a) its labeling failed to bear adequate directions for use; and (b) all statements required by the FDCA to appear on the label and labeling did not appear in the English language.

13. Defendant Maribel Quintero falsely represented to customers and victims to whom she administered the liquid silicone injections that these were safe when in fact they were not.

Method and Means of the Scheme and Artifice

14. As part of the scheme and artifice to defraud, the defendant Maribel Quintero would procure prospective clients for injection of the silicone for the purpose of affecting the structure of the buttocks by making false statements as to the qualifications of the defendant to install such devices, the identity and safety of the devices to be used and the effectiveness of the procedures.

15. As part of the scheme and artifice, the defendant Maribel Quintero would obtain these devices from outside the state of Texas or the materials used to make these devices came from outside the state of Texas.

16. As part of the scheme and artifice, the defendant Maribel Quintero would receive money for these procedures.

COUNT ONE

17. The allegations in paragraphs 1 through 16 are re-alleged and incorporated as if fully set forth in this paragraph.

18. On or about September 9, 2014, in the Southern District of Texas and within the jurisdiction of the Court, defendant,

MARIBEL QUINTERO

with the intent to defraud and mislead Erick Alejandro Garza, received in interstate commerce a

Class III device that was adulterated within the meaning of 21 U.S.C. § 351(f)(1), namely liquid silicone, and the defendant delivered and proffered delivery of the adulterated device to Erick Alejandro Garza for pay or otherwise.

In violation of Title 21, United States Code, Sections 331(c), 333(a)(2) and Title 18, United States Code, Section 2.

COUNT TWO

19. The allegations in paragraphs 1 through 16 are re-alleged and incorporated as if fully set forth in this paragraph.

20. On or about September 9, 2014, in the Southern District of Texas and within the jurisdiction of the Court, defendant,

MARIBEL QUINTERO

with the intent to defraud and mislead Erick Alejandro Garza, received in interstate commerce a device that was misbranded, namely liquid silicone, and the defendant delivered and proffered delivery of the misbranded device to Erick Alejandro Garza for pay or otherwise. The device was misbranded in the following ways:

a) its labeling failed to bear adequate directions for use (21 U.S.C. § 352(f)(1) and 21 C.F.R. § 801.5); and

b) all words, statements, and other information required by or under authority of the FDCA failed to be in the English language (21 U.S.C. § 352(c) and 21 C.F.R. § 801.15(c)(1)).

All this was in violation of Title 21, United States Code, Sections 331(c), 333(a)(2) and Title 18, United States Code, Section 2.

COUNT THREE

21. The allegations in paragraphs 1 through 16 are re-alleged and incorporated as if fully set forth in this paragraph.

22. On or about September 9, 2014, in the Southern District of Texas and within the jurisdiction of the Court, defendant,

MARIBEL QUINTERO

with the intent to defraud and mislead Humberto DeLeon Reyes, received in interstate commerce a Class III device that was adulterated within the meaning of 21 U.S.C. § 351(f)(1), namely liquid silicone, and the defendant delivered and proffered delivery of the adulterated device to Humberto DeLeon Reyes for pay or otherwise.

In violation of Title 21, United States Code, Sections 331(c), 333(a)(2) and Title 18, United States Code, Section 2.

COUNT FOUR

23. The allegations in paragraphs 1 through 16 are re-alleged and incorporated as if fully set forth in this paragraph.

24. On or about September 9, 2014, in the Southern District of Texas and within the jurisdiction of the Court, defendant,

MARIBEL QUINTERO

with the intent to defraud and mislead Humberto DeLeon Reyes, received in interstate commerce a device that was misbranded, namely liquid silicone, and the defendant delivered and proffered delivery of the misbranded device to Humberto DeLeon Reyes for pay or otherwise. The device was misbranded in the following ways:

a) its labeling failed to bear adequate directions for use (21 U.S.C. § 352(f)(1) and 21

C.F.R. § 801.5); and

b) all words, statements, and other information required by or under authority of the FDCA failed to be in the English language (21 U.S.C. § 352(c) and 21 C.F.R. § 801.15(c)(1)).

All this was in violation of Title 21, United States Code, Sections 331(c), 333(a)(2) and Title 18, United States Code, Section 2.

COUNT FIVE

On or about September 9, 2014, in the Southern District of Texas and within the jurisdiction of the Court, defendant,

MARIBEL QUINTERO

willfully and knowingly did enter and introduce, and attempt to enter and introduce, into the commerce of the United States, imported merchandise, that is two bottles of Remplisage by means of a false and fraudulent declaration in which the defendant **MARIBEL QUINTERO** falsely and fraudulently stated that the two bottles contained mineral oil whereas, in truth and fact, as defendant **MARIBEL QUINTERO** well knew, the said bottles contained Remplisage, an injectable filler.

In violation of Title 18, United States Code, Section 542.

COUNT SIX

On or about September 9, 2014, in the Southern District of Texas and within the jurisdiction of the Court, defendant,

MARIBEL QUINTERO

having been convicted of a crime punishable by imprisonment for a term exceeding one year, namely, in the 139th Judicial District of Hidalgo County, Texas, on November 9, 1995, in cause

number CR-1886-95-C, for Robbery, did knowingly and unlawfully possess in and affecting interstate and foreign commerce a firearm, namely, a Beretta Px4 Storm Pistol, 9mm in caliber.

In violation of Title 18, United States Code, Sections 922(g)(1) and 924(a)(2).

A TRUE BILL

FOREPERSON

KENNETH MAGIDSON
UNITED STATES ATTORNEY

Kimberly Ann Lee
ASSISTANT UNITED STATES ATTORNEY